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Dockets Management Branch
Food and Drug administration
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RE: ANDA Suitability Petition
Irinotecan Hydrochloride Injection, 20 mg/mL

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this Suitability Petition (the "Petition") in quadruplicate under Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act and 21 CFR §10.20, 10.30, and 314.93 to request the Commissioner of the Food and Drug Administration to make a determination that an Abbreviated New Drug Application may be submitted for Irinotecan Hydrochloride Injection, 20 mg/mL in a strength of 500 mg/25 mL single use vial.

A. Action Requested

The petitioner requests the Commissioner of the Food and Drug Administration to make a determination and to permit a change in the total drug content (strength) to allow for submission of an Abbreviated New Drug Application (ANDA) for Irinotecan Hydrochloride Injection, 20 mg/mL, in a strength of 500 mg/25 mL.

The basis of the Petition is the reference listed drug (RLD), Camptosar® Injection (Camptosar®), marketed by Pharmacia & Upjohn (now known as Pfizer Inc.). Camptosar® Injection, 20 mg/mL, is available in two strengths; a single use vial containing 40 mg/2 mL and 100 mg/5 mL of Irinotecan Hydrochloride. Pfizer received approval for the aforementioned strengths under NDA 20-571 on October 22, 1998.

B. Statement of Grounds

Section 505(j)(2)(C) of the Food, Drug and Cosmetic Act provides for submission of an ANDA for a new drug product that differs in strength from a RLD provided that FDA has approved a petition seeking permission to file such an application. The subject of this petition for Irinotecan Hydrochloride Injection is to permit a change in strength (total drug content per vial) from that of the RLD.

The RLD, Camptosar®, marketed by Pfizer Inc. is available as a vial containing 40 mg/2 mL or 100 mg/5 mL. The proposed drug product will be in the same concentration, 20 mg/mL, as the RLD, but in a strength of 500 mg/25 mL.

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Product	Dosage Form	Route of Administration	Strength
Pfizer's Camptosar® Injection	Solution	Intravenous	Irinotecan Hydrochloride 40 mg/2 mL and 100 mg/5 mL
Proposed Irinotecan Hydrochloride Injection	Solution	Intravenous	Irinotecan Hydrochloride 500 mg/25 mL

Camptosar® Injection is indicated as a component of first-line therapy in combination with 5-fluorouracil and leucovorin for patients with metastatic carcinoma of the colon or rectum. Camptosar® is also indicated for patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following initial fluorouracil-based therapy.

The proposed strengths contain the drug amount recommended in the approved labeling for dilution with 5% Dextrose Injection, USP, (preferred) or 0.9% Sodium Chloride Injection, USP, to a final concentration range of 0.12 to 2.8 mg/mL.

Camptosar® is currently approved in two fill sizes, 40 mg/2 mL and 100 mg/5 mL. However, the approved labeling for Camptosar® clearly contemplates the use of modified doses of 350 mg/m^2 (or 595 mg as starting dose, based on Average Body Surface Area of 1.7 m^2) to 300 mg/m^2 (or 510 mg as Dose Level–1) administered by slow intravenous infusion. The proposed strength, 500 mg total drug content per vial, will provide practitioners with convenient alternative to the currently approved strengths. A copy of the medical rationale is provided in **Attachment I.**

The proposed strength will allow preparation of approved modified Starting Dose of 350 mg/m^2 by using one vial each of 500 mg/25 mL and 100 mg/5 mL compared to the six 100 mg/5 mL vials of the reference listed drug. Similarly, for the modified Dose Level – 1 (300 mg/m^2) one vial each of 500 mg/25 mL and 40 mg/2 mL will be required compared to five vials of 100 mg/5 mL plus one vial of 40 mg/2 mL of the reference listed drug.

The proposed strength clearly conforms to the dosage modifications (Table 12, Attachment 1) and administration recommendations listed in the approved package insert of the reference listed drug. Since the need to open multiple vials will be reduced, the proposed drug product will minimize the potential for contamination resulting from the handling of the product, such as blood borne pathogens from cut fingers and glass particles. The proposed presentation will also provide a reduction in hazardous waste disposal and cost for the course of therapy.

The proposed drug is intended for use only as described in the **Indications** and **Dosage and Administration** sections of the approved labeling of the RLD. Draft labeling is provided in **Attachment II.**

Included in **Attachment III** is the package insert for Camptosar®, marketed by Pfizer Inc. The labeling for the proposed drug is identical to that of Pfizer's Camptosar®, but differs only with respect to the product name, dilution volume, the how-supplied statement, and the specific manufacturer's information.

The proposed strength (500 mg/25mL) does not pose questions of safety or efficacy because the unit dose formulation, the uses, the doses, and the route of administration are the same as those of the RLD. The only difference between the proposed products and the RLD is the strength (total drug content per vial). The proposed doses are reflected in Table 12 of the approved labeling of the RLD. For the above reasons, the undersigned requests that the Commissioner approve this petition and find that an application for Irinotecan Hydrochloride Injection, 500 mg/25 mL is suitable for submission as an ANDA.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact Statement

According to 21 CFR 10.30(b), the petitioner will, upon request by the Commissioner, submit economic impact information.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner, which are unfavorable to the Petition.

Sincerely,

Steve Richardson
Director, Regulatory Affairs
Mayne Pharma (USA) Inc.

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Attachment I: Medical Rationale
Attachment II: Draft labeling
Attachment III: Labeling for Camptosar® Injection